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EXAMINER

WARE, TODD

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 13

Application Number: 09/245,625
Filing Date: February 05, 1999
Appellant(s): BURCH ET AL.

Bruce M. Monroe Reg. No. 33,602
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 10, 2001.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that Group I; claims 1 and 10, Group II; claims 2, 3, and 11, Group III; claims 4, 20, and 21, Group IV; claims 5-9, 12, and 22, Group V; claims 14, 16, 17, and 19; Group VI; claims 13, 15, 18, and 25-29 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because the appellant is merely pointing out the differences in what the claims cover and the claims as listed by the appellant are not separately patentable. The claims are directed to an elastomeric polymer fiber, a container and the

fiber and methods of making the fiber where the fiber has a segmented core of soft and hard segments and is impregnated with a chemotherapeutic agent such as penicillin, sodium fluoride, stannous fluoride, or chlorhexidine. All claims require the same elastomeric polymer fiber imbibed with a chemotherapeutic agent.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,433,226	Burch	7-1995
5,098,711	Hill et al	3-1992

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-22 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burch (5,433,226; hereafter '226) in combination with Hill et al (5,098,711; hereafter '711).

Applicants claim a fiber and methods of making the fiber where a fiber having a segmented core of soft and hard segments is impregnated with a chemotherapeutic agent such as penicillin, sodium fluoride, stannous fluoride, or chlorhexidine.

'226 teaches dental floss fibers having a segmented core of hard and soft segments made of the compounds of the instant claims. '226 also teaches that this dental floss has a break elongation and tensile strength within applicants' ranges and that the fibers are in the form of multiple strands or filaments. '226 does not teach impregnating these dental floss fibers with a chemotherapeutic agent.

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'711 is relied upon for teaching multiple stranded or filamented nylon dental floss loaded with chemotherapeutic agents such as penicillin, sodium fluoride, stannous fluoride, or chlorhexidine prepared by dipping the floss into an agitated bath containing the therapeutic agent (column 21, line 30 – column 22, line 59 and table VI).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '226 and '711 with expectation of success, since both the floss of '226 and that of '711 utilize polymer fibers in the form of multiple strands or filaments, and the motivation that the antimicrobial agents of '711 would impart antimicrobial properties to the fibers of '226 thereby providing an effective means to deliver these antimicrobial agents to the oral cavity or gingiva and that such a floss would accommodate and clean the spacings of different dimensions between teeth while maintaining strength.

(11) *Response to Argument*

Applicants argue that since Hill ('711) does not teach imbibing or absorbing a chemotherapeutic agent into a fiber, the combination of Burch ('226) and '711 does not produce appellants' invention. It is well-known that fibers are made up of many individual strands. Imbibing is equivalent to coating unless a specific fiber size is recited as the therapeutic agent coats the multiple individual fiber strands within the unit as a whole. Indeed, page 4 of the instant specification provides a structure of a unit made up of multiple filaments. In any event, no criticality is expressed by the prosecution data to show criticality of agent imbibed in a fiber. Applicants do argue that the instant results

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are unexpected, since Example 1 of the specification shows that a conventional dental floss takes up 385 ppm of fluoride and the instant spandex floss takes up 2300 ppm of fluoride. However, it is unknown whether the "conventional dental floss" compared in Example 1 is the same dental floss of '711. Therefore, it is unclear whether the spandex dental floss would absorb more fluoride than the dental floss of '711. Indeed, '711 teaches that the floss disclosed therein provides for floss having surprisingly high concentrations of drug and that the amount of active agent loaded is effective to treat diseases (column 11, lines 45-63; column 14, lines 19-59; column 15, lines 3-22; column 19, lines 24-38; column 20, lines 28-41). Applicants have submitted that there is no evidence that the nylon used by '711 differs from the nylon used in other dental floss. However, '711 states that it is the construction of the dental floss or how the fibers are twisted into the finished floss that influences the amount of the compositions that can be loaded into the floss of '711.

Also, the scope of the claims is not commensurate with the scope of example 1. Example 1 utilizes spandex and sodium fluoride, while the claims are directed to an elastomeric polymer and a chemotherapeutic agent. Thus, it is unclear whether the results indicated in example 1 are applicable to all elastomeric polymers and all chemotherapeutic agents.

As the floss of '711 is the same "type" (i.e. fibers consisting of multiple filaments or strands) and the individual filaments which make up the floss each have drug providing for a unit that has drug containing filaments therein, the floss of '711 meets the requirements of the instant claims where the chemotherapeutic agent is imbibed.

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Therefore, the burden has been shifted to the applicants to provide evidence of non-obviousness.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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December 12, 2001

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